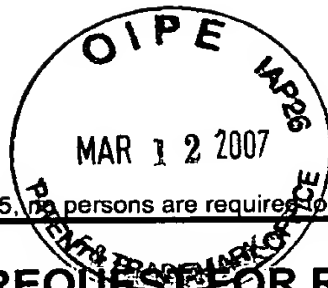


Doc Code: AP.PRE.REQ



PTO/SB/33 (07-05)

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

2943/56040-B/JPW/GJG

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on March 8, 2007Signature *Gary J. Gershik*Typed or printed name Gary J. Gershik

Application Number

09/826,069

Filed

April 4, 2001

First Named Inventor

Yaakov Naparstek

Art Unit

1644

Examiner

G. R. Ewoldt

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)☒ attorney or agent of record.  
Registration number 39,992☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_*Gary J. Gershik*  
SignatureGary J. Gershik

Typed or printed name

212-278-0400

Telephone number

March 8, 2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☐ \*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Docket No. 56040-B/JPW/GJG

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Yaakov Naparstek  
Serial No.: 09/826,069 Group Art Unit: 1644  
Filed : April 4, 2001 Examiner: G.R. Ewoldt  
For : PEPTIDES FOR THE TREATMENT OF SYSTEMIC LUPUS  
ERYTHEMATOSUS AND METHODS OF TREATING LUPUS  
ERYTHEMATOSUS

1185 Avenue of the Americas  
New York, New York 10036  
March 8, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SIR:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Pursuant to a July 12, 2005 Notice in the Official Gazette, applicants respectfully request that a panel of Examiners review the final rejection of the above-identified application which was set forth in a September 9, 2006 Final Office Action.

This Request is being filing concurrently with a Notice of Appeal in a separate paper.

**1) Claim 14 Is Entitled To March 20, 1997 Filing Date, Is Not Subject To Any Rejection Of Record, And Is Allowable.**

Applicant's July 27, 2006 Amendment on page 4 pointed out that claim 14 is supported by portions of the disclosure originating in a parent application having a March 20, 1997 priority date. Specifically, claim 14 is supported, *inter alia*, by page 4, lines 29-32; page 11, line 21 to page 12, line 14; and Figures 5, 6, 7 and 9 of the subject application. It is well settled that claims "fully supported under 35 U.S.C. 112 by the earlier parent

Applicants: Yaakov Naparstek  
Serial No.: 09/826,069  
Filed : April 4, 2001  
Page : 2

application have the effective filing date of that earlier parent application." M.P.E.P. §706.02(V)(B).

Because the sole rejection of claim 14 is an obviousness rejection relying on references dated after March 20, 1997, claim 14 is improperly included in that rejection.

In the September 8, 2006 Final Office Action, the Examiner does not contest that claim 14 is entitled to the March 20, 1997 effective filing date. Claim 14 is nonetheless included in the obviousness rejection based on post-March 20, 1997 references. This is improper. The post-March 20, 1997 references of the obviousness rejection cannot impact the patentability of claim 14 having a March 20, 1997 effective filing date.

Accordingly, claim 14 is not subject to any rejection of record and is understood to be allowable. A formal indication of allowance of claim 14 is respectfully requested.

**2) Rejection of Claim 11 Under 35 U.S.C. § 112, 1<sup>st</sup> paragraph**

On page 6 of the September 8, 2006 final Office Action, the Examiner rejected claim 11 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as allegedly introducing new matter. Examiner paraphrased claim 11 and concluded that the specification does not support claim 11.

Applicant respectfully disagrees. Except for its transitional phrase "consists essentially of," claim 11 is otherwise identical to claim 9 which has not been objected to. Both claims are supported literally by the specification, e.g. on page 5, lines 3-8, and exemplified on page 18, line 3 to page 19, line 10 as explained in the support section of Applicant's July 27, 2006 Amendment. Claim 11 is, thus, fully supported by the subject

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Page : 3

specification and this rejection is improper.

**3) Point #1 of Applicant's July 27, 2007 Reply Has Not Been Addressed, thus Requiring Withdrawal of the Rejection.**

In the September 8, 2006 Final Office Action, the Examiner maintained the rejection of claims 8-10, and added to the rejection claims 11-14\* , under 35 U.S.C. §103(a) as allegedly unpatentable over Gaubitz, M., et al., Journal of Autoimmunity, (1999), 11:495-501 ("Gaubitz") in view of U.S. Patent No. 6,228,363, issued May 8, 2001 (Naparstek) with a priority date of March 20, 1998 ("the '363 patent") and Madaio, M., et al., Journal of the American Society of Nephrology, (1996), 7:387-396 ("Madaio").

While Applicant maintains all of its arguments of record, noting that there is disagreement between the Examiner and Applicant, Applicant respectfully request the Pre-Appeal Brief Panel to focus on the one issue that remains unaddressed on this record. Applicant maintains that the record continues to lack an explanation of how the combined disclosure of the cited references teach the element of "extracorporeal treatment of plasma ... by affinity absorption column chromatography, wherein the column comprises [or as in claim 11: consists essentially of] a peptide having an amino acid sequence as set forth in SEQ. ID. NO. 1."

Specifically, nothing of record teaches or suggests the extracorporeal removal of antibodies that bind to a peptide represented by SEQ ID NO. 1. Applicant has pointed out this deficiency of the obviousness rejection in his July 27, 2007 reply.

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\* As noted herein, claim 14 has been improperly included in this rejection.

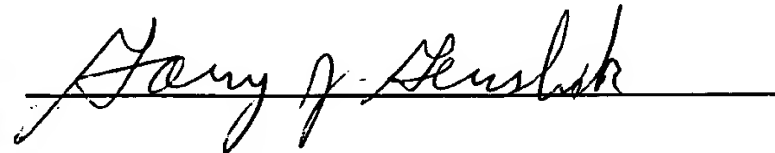
Applicants: Yaakov Naparstek  
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Filed : April 4, 2001  
Page : 4

Applicant respectfully submits that maintenance of the obviousness rejection is improper on this record. "Logic and sound reasoning" cannot supplant the fact that the peptide of SEQ ID NO. 1 (R38 peptide) is only disclosed in the cited references for administration to a patient. Nowhere do the cited references suggest selecting the R38 peptide to place on a column, or removing from a patient antibodies that bind the R38 peptide. Indeed, neither the September 8, 2006 final Office Action nor any prior Office Action offers a single citation showing otherwise. It is only in hindsight with the benefit of applicant's disclosure that the Examiner has come to believe the R38 peptide may be used in a column for extracorporeal removal of anti-R38 antibodies.

Applicant respectfully requests the Panel to withdraw this improper rejection.

No fee is deemed necessary in connection with the filing of this Pre-Appeal Brief Request For Review. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

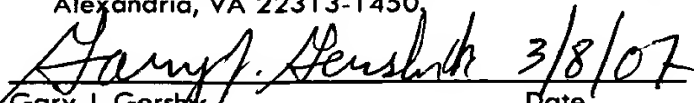
Respectfully submitted,



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 3/8/07  
Gary J. Gershik Date  
Reg. No. 39,992